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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,309	06/21/2001	Melissa K. Carpenter	090/002	9525
22869	7590	01/18/2005	EXAMINER	
GERON CORPORATION 230 CONSTITUTION DRIVE MENLO PARK, CA 94025			FALK, ANNE MARIE	
			ART UNIT	PAPER NUMBER

1632

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/888,309

Applicant(s)

CARPENTER ET AL.

Examiner

Anne-Marie Falk, Ph.D.

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 December 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 13 December 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 34-46.

Claim(s) withdrawn from consideration: 23-33 and 47.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Anne-Marie Falk
Anne-Marie Falk, Ph.D.
Primary Examiner
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Continuation Sheet (PTOL-303)

Continuation of 2. NOTE:

The proposed amendment raises new issues that would require new rejections. For example, the proposed amendments to Claims 34 and 35 would necessitate new grounds of rejection under 35 U.S.C. 112, second paragraph for Claims 36-46 because the claims recite “the system of claim 35” or the like, but Claim 35 is directed to “a plurality of cell populations”, not a “system.” Thus, the term “system” lacks antecedent basis. As another example, in Claim 41, “the second cell population” lacks antecedent basis.

Continuation of 5. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

At page 6 of the response, Applicants assert that the written description is based on two issues that do not raise a patentability issue under 35 U.S.C. 112, second paragraph. Applicants’ characterization of the written description rejection is inaccurate because the rejection is based on lack of support in the original disclosure for the particular **combination** of two cell populations now being claimed. The rejection is a New Matter rejection and does not rely on the issue regarding place of manufacture or time of possession, as Applicant states. The combination of the two cell populations is not described in the specification and therefore constitutes new matter, for lack of written description.

At page 7 of the response, Applicants assert that when a product has multiple components, it is not necessary for the components to be used together. Applicants point to Claim 22 of U.S. Patent No. 6,740,649 for teaching an article of manufacture comprising 3 components. Applicants argue that the components are not used at the same time. The Examiner notes that each patent application is considered on its own merits, based on the particular facts of the case, and will not comment further, as the facts and evaluation of other cases do not pertain to the instant case under examination.

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Continuation Sheet (PTOL-303)

At page 7 of the response, Applicants argue that the present application discloses and enables a number of uses for the two components of the claims. Applicants point to the use of hES cells to produce neural cells, which may then be used therapeutically or to prepare a pharmaceutical composition. First it is noted that the specification does not provide a teaching of a neural cell composition that can be used therapeutically. Second, since the specification does not provide such a teaching it clearly does not teach how to use hES cells to produce a neural cell composition that can be used therapeutically. Furthermore, it is maintained that the specification must teach how to use the claimed combination of two cell populations, which it does not.

At page 8, paragraph 1 of the response, Applicants argue that the hES cells can be used to generate an antibody specific for undifferentiated hES cells and that differentiated embryonic cells can be used to negatively select antibodies that are not specific for hES cells. Applicants point to the specification at page 21, lines 16-20 which broadly contemplates using “pPS” cells for positive selection and “differentiated embryonic cells” for negative selection, but notably does not contemplate using the claimed combination of cell populations.

At page 8, paragraph 2 of the response, Applicants assert that the two components of the claim can be used in generating subtraction libraries. Applicants point to the specification at page 21, lines 21-25 which broadly contemplates using “differentiated pPS cells” and “undifferentiated cells”, but again notably does not contemplate using the claimed combination of cell populations. Moreover, generation of subtraction libraries would not be considered a specific and substantial utility, and therefore would not be evaluated under the “how to use” requirement of 35 U.S.C. 112, first paragraph. Rather, the specification must teach how to use the claimed invention for a specific and substantial utility within the context of 35 U.S.C. 101.

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Continuation Sheet (PTOL-303)

Where Applicant's arguments are directed to the claim amendments Applicant's arguments have been fully considered but are moot because the amendments have not been entered for the reasons noted above.

Therefore, all standing grounds of rejection are maintained for reasons of record.

At page 9 of the response, Applicants propose filing an RCE for the purpose of switching to a non-elected invention. Such a switch would require a new search and examination of a distinct and independent invention, having substantially different claim limitations, and thus would lead to protracted examination of the instant application. Therefore, the proposed switch will not be granted.

At page 9 of the response, Applicants request a further interview. Applicant has already been granted an interview after final rejection and a further interview is not warranted and will not be granted.

See MPEP 713.09.